

In re Application of David J. Brayden  
Application No. 09/386,266

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### **REMARKS**

Reconsideration of the allowability of the present application is requested respectfully.

#### **Status of the Claims**

Claims 35 to 46 were acted upon by the Examiner in the Office Action dated October 18, 2004. Claims 35, 39, 41 and 45 have been amended. No claims have been cancelled. No claims have been added. Accordingly, Claims 35 to 46 are presented for examination.

#### **Support for Claim Amendments**

Support for the amendment to Claim 35 is found on page 5, lines 1 to 7.

Support for the amendment to Claim 41 is found on page 5, lines 8 to 12.

Support for the amendments to Claims 39 and 45 is found on page 5, lines 13 to 21, and in originally filed Claim 15, respectively.

### **ARGUMENTS**

In response to the Examiner's Final Office Action dated October 18, 2004, Applicant respectfully traverses the Examiner's rejection of Claims 35 to 46.

#### **The §112, First Paragraph, Rejections of Claims 35 and 41**

The Examiner has rejected Claims 35 and 41 under 35 U.S.C. §112, first paragraph, as containing new subject matter and for failing to demonstrate that at the time of filing applicant was in possession of the presently claimed invention. In particular, the Examiner asserts that the specification lacks support for an "immune response to an antigen" as recited by Claims 35 and 41.

In response, Claims 35 and 41 have been amended to recite an "immune response" instead of an "immune response to an antigen". Claims 35 and 41 have been

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further amended to recite “microparticles comprising at least one antigen entrapped or encapsulated in biodegradable polymer”. Support for the amendment to Claim 35 is found on page 5, lines 1 to 7. Support for the amendment to Claim 41 is found on page 5, lines 8 to 12.

In view of these amendments applicant respectfully requests that the rejection of Claims 35 and 41 under 35 U.S.C. §112, first paragraph, be withdrawn.

**The §112, Second Paragraph, Rejections of Claims 35 to 46**

The Examiner has rejected Claims 35 to 46, under 35 U.S.C. §112, second paragraph, as being indefinite, for failing to particularly point out and distinctly claim the invention.

Claim 35 has been deemed vague for reciting an “immune response to an antigen” without the step of administering an antigen. In response, as noted above, Claim 35 has been amended to recite “A method of inducing a T<sub>H</sub>1 polarized immune response comprising parenterally administering to a subject microparticles comprising at least one antigen entrapped or encapsulated in a biodegradable polymer, wherein said microparticles are sized such that the average diameter of said microparticles is from about 2.2 μm to about 4.3 μm.” In view of this amendment applicant respectfully requests that the rejection of Claim 35, and those claims dependent thereon (Claims 36 to 40), under 35 U.S.C. §112, second paragraph, be withdrawn.

Claim 41 has been deemed vague for reciting a vaccine formulation for enhancing an “immune response to at least one antigen” without comprising “at least one antigen”. In addition, for clarity, the Examiner has also suggested that Claim 41 be amended to recite “..microparticles, wherein said microparticles are sized...”. In response, as noted above, Claim 41 has been amended to recite “A vaccine formulation for enhancing a T<sub>H</sub>1 immune response and adapted for parenteral administration comprising a pharmaceutically acceptable carrier and a

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pharmaceutically effective amount of microparticles comprising at least one antigen entrapped or encapsulated in a biodegradable polymer, wherein said microparticles are sized such that the average diameter of said microparticles is from about 2.2  $\mu\text{m}$  to about 4.3  $\mu\text{m}$ ". In view of these amendments applicant respectfully requests that the rejection of Claim 41, and those claims dependent thereon (Claims 42 to 46), under 35 U.S.C. §112, second paragraph, be withdrawn.

The Examiner has asserted that Claim 37 has improper antecedent basis for the term "the biodegradable polymer" because Claim 35, from which Claim 37 depends, does not recite a "biodegradable polymer". Claim 35 has been amended to recite "a biodegradable polymer". In view of this amendment applicant respectfully requests that the rejection of Claim 37 under 35 U.S.C. §112, second paragraph, be withdrawn.

The Examiner has asserted that Claim 43 has improper antecedent basis for the term "the biodegradable polymer" because Claim 41, from which Claim 43 depends, does not recite "a biodegradable polymer". As noted above, Claim 41 has been amended to recite "a biodegradable polymer". In view of this amendment applicant respectfully requests that the rejection of Claim 43 under 35 U.S.C. §112, second paragraph, be withdrawn.

The Examiner has asserted that Claim 45 has improper antecedent basis for the term "the antigen" because Claim 41, from which Claim 45 depends, does not recite a "an antigen". Rather Claim 41 recites "at least one antigen". Claim 45 has been amended to recite "at least one antigen". In view of this amendment applicant respectfully requests that the rejection of Claim 45 under 35 U.S.C. §112, second paragraph, be withdrawn.

The Examiner has asserted that Claim 45 is indefinite for reciting a vaccine formulation comprising a *B. pertussis* antigen, while Claim 41, from which Claim 45 depends, recites a vaccine formulation lacking an antigen. Claim 41 has been amended to recite, "A vaccine formulation ...comprising a pharmaceutically acceptable carrier and a pharmaceutically effective amount of microparticles comprising at least one

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antigen entrapped or encapsulated in a biodegradable polymer...". Accordingly, presently amended Claim 41 now recites a vaccine formulation comprising "at least one antigen". In view of this amendment applicant respectfully requests that the rejection of Claim 45 under 35 U.S.C. §112, second paragraph, be withdrawn.

The Examiner has asserted that Claim 46 is indefinite for reciting a vaccine formulation with "...each subpopulation comprising a different antigen...", while Claim 41, from which Claim 46 depends, recites a vaccine formulation lacking an antigen. Claim 41 has been amended to recite, "A vaccine formulation ...comprising a pharmaceutically acceptable carrier and a pharmaceutically effective amount of microparticles comprising at least one antigen entrapped or encapsulated in a biodegradable polymer...". Accordingly, presently amended Claim 41 now recites a vaccine formulation comprising "at least one antigen". In view of this amendment applicant respectfully requests that the rejection of Claim 46 under 35 U.S.C. §112, second paragraph, be withdrawn.

A favorable action on the merits is requested respectfully. Applicant respectfully requests that the Examiner contact the undersigned by telephone before issuing any further actions.

Respectfully submitted,

  
Jonathan M. Dermott, Ph.D.  
Registration No. 48,608

SYNNESTVEDT & LECHNER LLP  
2600 Aramark Tower  
1101 Market Street  
Philadelphia, Pennsylvania 19107  
(215) 923-4466